

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant

L. DUMOUTIER, et al.

Serial No.

09/751,797

Filed

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December 29, 2000

For

ISOLATED NUCLEIC ACID MOLECULES WHICH

ENCODE T CELL INDUCIBLE FACTORS (TIFs), THE

PROTEINS ENCODED, AND USES THEREOF

Art Unit

1644

Examiner

Philip Gambel

November 13, 2003

ATTN: Special Program Examiner TC 1600

Hon. Commissioner of Patents

P.O. Box 1450

Alexandria, VA 22313-1450

# PETITION TO MAKE SPECIAL (37 CFR § 1.102, MPEP § 708.02 (II))

Pursuant to 37 CFR § 1.102 and MPEP § 708.02 (II), applicants are petitioning the USPTO to make this application special because of actual infringement. It is the applicants' belief that there is at least one infringing product on the market. Applicants have made a rigid comparison of the suspected infringing product(s) with the claims of the application and, in applicants' opinion, some of the pending claims are unquestionably infringed. Applicants have also made a careful and thorough search of the prior art.

Applicants have become aware of products sold by Peprotech, Inc. through its catalog, described as "Human IL-22" and "Murine IL-22," also known as "T cell-derived inducible factor (ILTIF)." The subject matter claimed in the above referenced application is known as ILTIF as well as IL-22. Applicants thus compared their instant claims against the Peprotech products, and have concluded that at least one claim is unquestionably infringed.

A comparison of the amino acid sequences of the Peprotech Human IL-22 and Murine IL-22 products with the specific amino acid sequences disclosed in the subject application shows that they are identical, with only one difference, i.e., Peprotech's products are devoid of the N-terminal's 1<sup>st</sup> 32 amino acids of applicants' disclosed amino acid sequence.

The Peprotech materials describe the proteins as "recombinant proteins." As such, their production must, by definition, rely on isolated nucleic acid molecules which encode the relevant proteins. This is precisely what applicants claim. Further, the absence of the first 32 amino acids in the Peprotech products is believed irrelevant. The identity of the Peprotech amino acid sequences with the amino acid sequence disclosed by applicants clearly suggest that the nucleic acid molecules used by Peprotech, have a complimentary sequence which would hybridize, under stringent conditions, to at least one of the nucleic acid molecules recited in applicants' claims. Pursuant to 35 USC §271(a), this "use" is considered infringement.

Applicants have also made a careful and thorough search of the prior art and refer to the information disclosure statement that was filed in this case on June 27, 2001, pursuant to 37 CFR § 156, § 1.97(c). Furthermore, Ebner et al. (US 2003/0003545 A1) is a U.S. patent application cited by the Examiner in this case. None of these references are believed by the applicants to be relevant, i.e., it is believed that the claims are patentable over these references.

Pursuant to 37 CFR 1.17(h), enclosed please find a filing fee for \$130.00. Authorization is given to make appropriate fee adjustments, if necessary to deposit account 500624 if the amount of the check is incorrect.

Favorable action on this petition is requested.

Respectfully submitted,

FULBRIGHT & JAWORSKI, L.L.P.

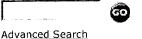
Norman D. Hanson

Registration No. 30, 946





### Pr duct Search



## **Human Growth Factors & Cytokines**

Recombinant Human Interleuki-22

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**Description:** Human IL-22 also known as T cell-derived inducib

factor (ILTIF), is a cytokine that is structurally related to IL-10. Studies have shown that IL-22 induces acute-phase reactants in vitro and in vivo This susgests that this cytokine contributes to the regulation of inflammatory responses. Recombina Human IL-22 is a 16.8 kDa protein consisting of

147 amino acid residues.

Catalog #: 200-22

Source: E.coli

**Formulation:** The sterile filtered solution was lyophilized from 1

mM NaCitrate, pH 4.0.

**Stability:** The lyophilized protein is stable for a few weeks a

room temperature, but best stored at -20°C. Reconstituted IL-22 should be stored in working

aliquots at -20<sup>0</sup>C.

Purity: Greater than 97% by SDS-PAGE. Endotoxin level

less than 0.1 ng per  $\mu g$  (1EU/ $\mu g$ ).

**Reconstitution:** We recommend a quick spin followed by

reconstitution in water to a concentration of 0.1-1 mg/ml. It is recommended that further dilutions b made into buffer containing carrier protein or medium containing serum. This solution can then be diluted into other buffers and stored at 40C for

week or stored at -20°C for future use.

Biological Activity: Recombinant Human IL-22 activates STAT following

receptor ligand interaction.

AA Sequence: MAPISSHCRL DKSNFQQPYI TNRTFMLAKE

ASLADNNTDV RLIGEKLFHG VSMSERCYLM KQVLNFTLEE VLFPQSDRFQ PYMQEVVPFL ARLSNRLSTC HIEGDDLHIQ RNVQKLKDTV

KKLGESGEIK AIGELDLLFM SLRNACI

PubMed Link: IL-22

Country of Origin: USA

Size A

 $2 \mu q$ 

\$65 US

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 Size B
 10 μg
 \$170 US

 Size C
 1 mg
 \$4800 US

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# Murine & Rat Growth Factors & Cytokines Recombinant Murine Interleukin-22

Description: Murine IL-22 also known as T cell-derived inducib

factor (ILTIF), is a cytokine that is structurally related to IL-10. Studies have shown that IL-22 induces acute-phase reactants *in vitro* and *in vivo* This suggests that this cytokine contributes to the regulation of inflammatory responses. Recombina Murine IL-22 is a 16.7 kDa protein consisting of

147 amino acid residues.

**Catalog #:** 210-22

Source: E.coli

**Formulation:** The sterile filtered solution was lyophilized from 1

mM NaCitrate, pH 4.0.

Stability: The lyophilized protein is stable for a few weeks a

room temperature, but best stored at  $-20^{\circ}$ C. Reconstituted IL-22 should be stored in working

aliquots at  $-20^{\circ}$ C.

**Purity:** Greater than 97% by SDS-PAGE and HPLC

analyses. Endotoxin level is less than 0.1 ng per p

 $(1EU/\mu g)$ .

**Reconstitution:** We recommend a quick spin followed by

reconstitution in water to a concentration of 0.1-1.0mg/ml. It is recommended that further dilutior be made into buffer containing carrier protein or medium containing serum. This solution can then be stored at  $4^{0}$ C for 1 week or  $-20^{0}$ C for future us

Biological Activity: No data available at this time.

AA Sequence: MLPVNTRCKL EVSNFQQPYI VNRTFMLAKE

ASLADNNTDV RLIGEKLFRG VSAKDQCYLM KQVLNFTLED VLLPQSDRFQ PYMQEVVPFL TKLSNQLSSC HISGDDQNIQ KNVRRLKETV KKLGESGEIK AIGELDLLFM SLRNACV

PubMed Link: IL-22+AND+mouse

Country of Origin: USA

**Size A** 2 μg \$65 US

**Size B** 10 μg \$170 US

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Size C

1 mg \$4800 US

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